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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,091	08/06/2003	Anne M. Pianca	20334/0209347-US0	6980

50638 7590 06/03/2010
Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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06/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/635,091	Applicant(s) PIANCA ET AL.	
	Examiner MICHAEL KAHELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,10-19 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,10-13,22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 6, 10-13, and 22-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claims 1 and 27, the examiner was unable to find support for a tubular outer covering or inner core that "extend[s] along the entire length of the body." Although Figures 4 and 5 appear to show a portion of the stylet having a tubular outer covering, nothing in the disclosure appears to indicate that this configuration extends along the *entire* length of the structure. Similarly, in regards to claim 22, the examiner was unable to find support for varying diameter from one end to the other.

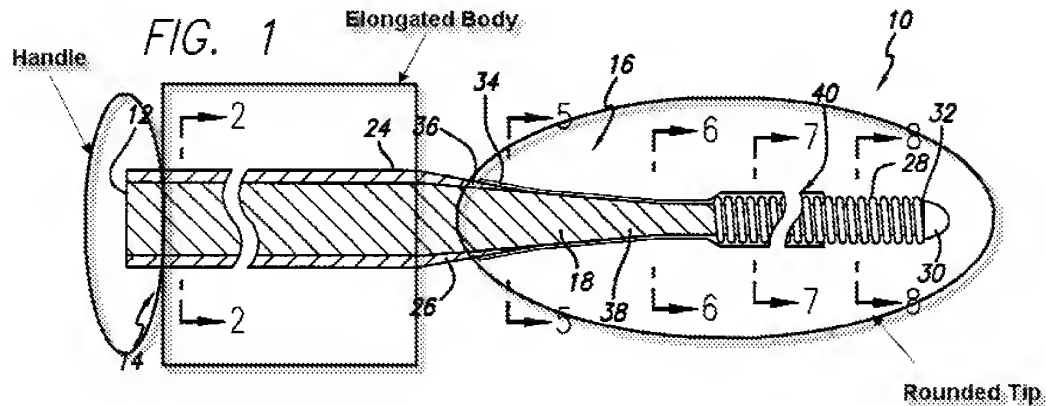
Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 10, 11, 23, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrera (US 6,165,140, hereinafter “Ferrera”).



5. In regards to claim 1, Ferrera discloses a stylet comprising an elongated body (above); and a handle disposed on the proximal end of the body (please see figure above - the noted region is a "handle" because it is capable of being gripped); wherein the body comprises an outer covering that is a tube extending along the entire length of the body (24) made of metal (col. 3, lines 20-25) and having a solid annular lateral cross-section (Fig. 2); wherein the body also comprises a solid inner core (12) surrounded by the outer covering and extending along the length of the body (see figure above; although Ferrera discloses an inner core that extends along the *entire* length of the body, the examiner is not considering claim 1 to be limited as such; see claim 27) made of inner core material (col. 3, lines 1-5); wherein the outer diameter of the body is isodiametric (see above; although Ferrera discloses a body that isodiametric along its entire length, the examiner is not considering the claim to require an outer diameter along the length of the body that is isodiametric along the *entire* length due to

Applicant's use of both "along the length" and "along the entire length", e.g., claims 1 and 27 -- this varying language must indicate varying scope or claim 27 fails to further limit claim 1); and wherein the outer and inner materials have different elastic and buckling properties (by virtue of the outer material being stainless steel and the inner material being Nitinol).

6. In regards to claim 10, the inner core (12) and outer covering (24) each have substantially constant thicknesses along the length of the stylet from the handle to the distal end (see figure above).

7. In regards to claim 11, the inner core and outer material possess the claimed properties because they are materials disclosed by Applicant as possessing these properties (Nitinol and stainless steel, respectively).

8. In regards to claim 23, the stylet has a solid cross-section along the length of the body (Figs. 1 and 2).

9. In regards to claims 25 and 26, the stylet further comprises a rounded tip coupled to the distal end of the body (see figure above) that is directly coupled to the distal end of the body (via 36 and 34). Under this interpretation, the outer covering includes element 36.

10. In regards to claim 27, the inner core extends along the entire length of the body (see figure above).

11. Claims 1, 6, 10, 22, 23, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamauchi et al. (US 5,069,226, hereinafter "Yamauchi").

12. In regards to claims 1 and 27, Yamauchi discloses a stylet comprising an elongated body (Fig. 1); and a handle disposed on the proximal end of the body (the end region is a "handle" because it is capable of being gripped); wherein the body comprises an outer covering that is a tube extending along the entire length of the body (element 12 excluding the rounded tip regions) made of metal (col. 3, lines 29-39 -- the outer covering comprises metal) and having a solid annular lateral cross-section (Fig. 1; col. 3, lines 21-23); wherein the body also comprises a solid inner core (11) surrounded by the outer covering and extending along the length of the body (Fig. 1) made of inner core material (col. 3, lines 46-53); wherein the outer diameter of the body is isodiametric (col. 3, line 22); and wherein the outer and inner materials have different elastic and buckling properties (by virtue of the outer material being metal-doped epoxy and the inner material being Ti-Ni alloy).

13. In regards to claims 6 and 22, the inner core and outer covering have variable diameters along the length of the body from one end to the other such that the outer diameter of the body remains isodiametric (Fig. 1, col. 3, lines 13-24).

14. In regards to claim 10, the inner core and outer covering have substantially constant thicknesses along the length of the body (Fig. 1, left end; the claim does not require substantially constant thickness along the entire length).

15. In regards to claim 23, the stylet has a solid lateral cross-section along the length of the body (Fig. 1; col. 3, lines 21-22).

16. In regards to claims 25 and 26, the stylet comprises a rounded tip coupled directly to the distal end of the stylet (Fig. 1).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 2-4, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera in view of Reynolds et al. (US 7,074,197, hereinafter "Reynolds"). Ferrera discloses the essential features of the claimed invention except for expressly disclosing that the inner core or outer covering is one of the claimed stainless steel alloys; an outer covering made of nitinol; or an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve. However, Reynolds teaches a means for attaching two different metals of a composite stylet structure (Fig. 2) comprising an outer sheath made of nitinol (26; col. 3, lines 51-60); an inner core or outer covering made of the claimed stainless steel alloys (24; col. 3, line

44); and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve (col. 4, lines 3-29) to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the tortuous anatomy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ferrera’s invention by providing a stylet having an outer sheath or inner core made of nitinol, an outer covering or inner core made of the claimed stainless steel alloys, and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the tortuous anatomy.

20. Claims 2-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi in view of Reynolds et al. (US 7,074,197, hereinafter “Reynolds”).

Yamauchi discloses the essential features of the claimed invention including a Ni-Ti alloy core, but does not expressly disclosing that the inner core or outer covering is one of the claimed stainless steel alloys; an outer covering made of nitinol; or an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve. However, Reynolds teaches a means for attaching two different metals of a composite stylet structure (Fig. 2) comprising an outer sheath made of nitinol (26; col. 3, lines 51-60); an inner core or outer covering made of the claimed stainless steel alloys (24; col. 3, line 44); and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve (col. 4, lines 3-29) to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the

tortuous anatomy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Yamauchi's invention by providing a stylet having an outer sheath or inner core made of nitinol, an outer covering or inner core made of the claimed stainless steel alloys, and an inner core that has been pre-stressed to operate on the compression side of the stress-strain curve to provide the predictable result of providing the desired mechanical characteristics for "pushability" through the tortuous anatomy.

21. Claims 6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera in view of Yamauchi. Ferrera discloses the essential features of the claimed invention except for explicitly indicating that the inner core has a variable diameter from one end to the other and the outer covering has a variable diameter from one end to the other such that the outer diameter of the body remains isodiametric. However, Yamauchi teaches that it is known to provide stylets with an inner core that has a variable diameter from one end to the other and an outer covering that has a variable diameter from one end to the other such that the outer diameter of the body remains isodiametric (Fig. 1) to provide the predictable results of both steerability and rigidity (col. 2, lines 10-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ferrera's invention by providing a stylet with an inner core that has a variable diameter from one end to the other and an outer covering that has a variable diameter from one end to the other such that the outer diameter of the body remains isodiametric to provide the predictable results of both steerability and rigidity.

22. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera (or Yamauchi) in view of Fields et al. (US 5,357,961, hereinafter "Fields"). Ferrera (or Yamauchi) discloses the essential features of the claimed invention except for a handle having an outer diameter larger than the outer diameter of the body. However, Fields teaches that it is well known in the art to provide stylet members such as Ferrera's (or Yamauchi's) with handles having a larger outer diameter than the stylet body (38) to provide the predictable results of more easily gripping and manipulating the narrow stylet element. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ferrera's (or Yamauchi's) invention by providing the body with a handle having a larger outer diameter than the stylet body to provide the predictable results of more easily gripping and manipulating the narrow stylet element.

Response to Arguments

23. Applicant's arguments with respect to claims 1-4, 6, 10-13, and 22-27 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. Applicant argued that support for an inner core and outer sheath that extend along an entire length of the stylet is provided by Figures 4 and 5 because these show an inner core and outer covering that extend along the entire length of the portions shown, and these are unspecified portions that can be any portion of the stylet. The examiner agrees that the core and covering of Figures 4 and 5 are shown to extend along the entire portion shown, but the examiner respectfully disagrees that written description support has been provided to indicate that this cross section corresponds to

any or all longitudinal positions along the stylet. For instance, nothing indicates that this core does not end at some arbitrary point from either end of the stylet, serving as a “joint” between pure core material (*e.g.*, at the distal end) and pure outer covering material (*e.g.*, at the proximal end). See, *e.g.*, Figures 1-4 of Reynolds. Applicant further argued, in regards to the previous art rejections, that Ferrera fails to disclose an isodiametric body. However, as indicated above, the examiner is considering only the isodiametric portion of Ferrera’s stylet to be the claimed “body” element (nothing in the claim language precludes an additional stylet element distal to the “body”).

Furthermore, the claims do not recite that the stylet is isodiametric along its entire length. Therefore, an alternative interpretation would be to consider the entire stylet to be the “body” with at least a portion of the lead being isodiametric (*i.e.*, the outer diameter of the body is isodiametric over the portion proximal to element 36). Similarly, Applicant argued that the sheath does not extend over the entire length of the body with constant thickness. However, please note the new interpretation of Ferrera above wherein the “body” is considered to be the isodiametric portion of the stylet -- the sheath extends along the entire length of this body and has a constant thickness. The claim is a “comprising” claim and thus can include other elements, such as the portions including and distal to element 36.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762